

REMARKS

Claims 1-17, and 31-40 are currently pending in this application. By this Amendment, claim 1 has been amended; claims 31-40 have been added; and claims 18-30 have been cancelled herein.

Applicant disagrees with all statements made in the Final Office Action even if they are not specifically addressed herein.

No new matter has been added via these amendments or new claims. Support for newly added claims 34-41 can be found at least at page 7, paragraph [0031], lines 8-12. Support for new claim 33 can be found at least at page 7, paragraph [0032], lines 1-4. Support for new claims 31 and 32 can be found at least at page 7, paragraph [0031], lines 6-8; and page 12, paragraph [0053], lines 1-2. At least those two passages also provide support for the amendment to claim 1. Specifically, those two passages discuss that “the period of time allows the gastro-intestinal (GI) tract to fully recover from the effects of any anesthetics used” and “any sedative used during the ablation procedure will wear off and the GI tract of the patient will regain functionality”. These two passages imply that the GI tract would have to have been impaired, and therefore they provide support for the amendments to claim 1.

§ 103 Rejection of the Claims

Claims 1-11 and 16-17 have been rejected under 35 U.S.C. § 103(a) as being obvious over Edwards U.S. Patent No. 6,405,732 (referred to herein as “Edwards ‘732”) in view of Edwards, U.S. Patent No. 6,254,598 (referred to herein as “Edwards ‘598”). Applicant respectfully traverses this rejection.

Although Applicant does not concede the correctness of the rejection, claim 1 has been amended herein to add the step of “temporarily impairing functionality of the gastro-intestinal tract” and specifying that the time period “is sufficient to allow the gastro-intestinal tract to regain functionality”. Applicant respectfully submits that neither Edwards ‘732 nor Edwards ‘598 disclose or suggest these elements.

Applicant respectfully submits, contrary to the assertion of the Final Office Action, that Edwards ‘598 does not disclose determining a first and second acid level. Edwards ‘598 does mention a pH monitoring catheter as one of the many possibilities for

an elongated medical device that may be utilized with the basket assembly of Edwards '598. However, Edwards '598 is only concerned with sensors for monitoring temperature (Column 9, lines 14-27), and therefore one of skill in the art would not have been motivated to pick a pH catheter from all of the various possibilities of an elongated medical device. Although a pH monitoring catheter may be capable of monitoring pH, there is nothing in Edwards '598 that would lead one of skill in the art to do so, and certainly not to determine a first acid level and a second acid level.

Similarly, Edwards '732 does not disclose or suggest determining a first acid level and a second acid level. Edwards '732 does discuss other diagnostic methods that can be utilized, but only includes visualization of the interior surface of the esophagus using an endoscope, visualization of the interior surface of the esophagus using ultrasonography, and impedance measurement (Column 15, lines 23-33), temperature measurement, sphincter contractile force measurement via manometry (Column 16, lines 3-5). Neither disclosure nor anything else in Edwards '732 would lead one of skill in the art to determine a first and second acid level.

Furthermore, the combination of Edwards '732 and Edwards '598 also does not disclose or suggest determining a first acid level and a second acid level. Even if Edwards '732, Edwards '598 or the combination thereof suggested determining a first acid level and a second acid level, there is certainly nothing in either reference or the combination thereof that would suggest that a second acid level be determined after a time period that allows the gastrointestinal tract to regain functionality.

The Final Office Action states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a pH monitoring catheter in the device of Edwards '732 in view of the teaching of Edwards '598 since the device of Edwards '732 is also for treating a patient with a hyperacid condition (Final Office Action page 3). Applicant respectfully disagrees with this assertion because Edwards '732 discloses its own methods of diagnostic monitoring; visualization of the interior surface of the esophagus using an endoscope, visualization of the interior surface of the esophagus using ultrasonography, and impedance measurement (Column 15, lines 23-33), temperature measurement, sphincter contractile force measurement via manometry (Column 16, lines 3-5). With such monitoring methods already in place, one

of skill in the art would not have been motivated to modify or replace the methods of Edwards '732 with those of Edwards '598. Furthermore, even if Edwards '598 were properly combined with Edwards '732, as discussed above, there is still no suggestion about determining acid levels at two different times.

With respect to the added element of amended claim 1, that the second acid level is determined after a period of time that allows the gastro-intestinal tract to regain functionality, Applicant respectfully submits that neither Edwards '732 nor Edwards '598 provide any disclosure or suggestion with regard to such a time frame. The treatment of Edwards '732 functions by ablating nerve fibers or the nerve pathways leading from the gastric receptors to the LES. The treatment of Edwards '598 functions by creating cell necrosis in sphincter tissue underlying a sphincter mucosal layer (Column 3, lines 26-28). Because the method of Edwards '732 and Edwards '598 function in entirely different manners than the method of claim 1, one of skill in the art would not have been motivated to modify the methods of Edwards '732 and Edwards '598 to wait for a period of time applicable to the different functioning method of claim 1.

With respect to originally rejected claim 5, the Final Office Action asserts that it would have been obvious to one of ordinary skill in the art to measure pH at any desirable time after the ablation procedure. Applicant respectfully asserts that this statement utilizes impermissible hindsight reconstruction in concluding that the particular time chosen in claim 5, one week, would have been obvious to one of ordinary skill in the art only because it would have been obvious to measure at any desirable time. Claim 5 is not claiming measuring at any desirable time, but is instead claiming measuring at one week after ablation. The desirability of this particular time is evident only in light of Applicant's specification, and therefore it could only be obvious if hindsight reconstruction were utilized.

Because the rejected claims 2-17, and new claims 31-33 are dependent on claim 1, Applicant respectfully asserts that they are also not obvious over Edwards '732 in view of Edwards '598. Applicant also asserts that there may be other, independent reasons why claims 2-17, and 31-33 are not obvious over Edwards '732 in view of Edwards '598, even if those reasons are not discussed herein.

With respect to newly added claims 34-40, Applicant respectfully asserts that they are also not obvious over Edwards '732 in view of Edwards '598. The Final Office Action noted, with respect to original claim 17, that since the device of Edwards '598 includes a pH monitoring catheter, it inherently ablates additional stomach tissue based on a comparison of the second esophageal acid level. Applicant strongly disagrees with this statement.

Both Edwards '732 and Edwards '598 utilize different methods of monitoring the methods disclosed therein. Edwards '732 utilizes visualization of the interior surface of the esophagus using an endoscope, visualization of the interior surface of the esophagus using ultrasonography, and impedance measurement (Column 15, lines 23-33), temperature measurement, sphincter contractile force measurement via manometry (Column 16, lines 3-5); and Edwards '598 uses sensors for monitoring temperature (Column 9, lines 14-27).

Neither of those references nor the combination thereof would lead one of skill in the art to base the success of a procedure on a comparison of two acid levels. The only way that claims 34-40 could be obvious over Edwards '732 in view of Edward '598 is through the use of impermissible hindsight reconstruction. The method of Applicant's claim 34 seemingly rendering this comparison obvious is not an appropriate motivation to modify the cited references. Furthermore, the fact that the references can be modified is not a proper motivation for obviousness (MPEP § 2143.01(II)), but instead there must be some motivation to make the modification.

Based at least on these comments, Applicant respectfully asserts that claims 34-40 are not obvious over Edwards '732 in view of Edwards '598.

In view of the foregoing amendments and comments, Applicant respectfully requests reconsideration and allowance of the claims as all rejections have been overcome. Early notice of allowability is kindly requested.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 50-3964.

Respectfully submitted,

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